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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,421	04/23/2002	John D Puskas	45044-267442	3303
23370	7590	11/02/2005		
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			EXAMINER GREENE, DANA D	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

RTN

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	09/980,421		PUSKAS, JOHN D	
	<b>Examiner</b>		<b>Art Unit</b>	
	Dana D. Greene		3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/4/02, 11/26/04, 3/4/05, 3/2/05</u>                                      | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicant's election without traverse of Group I in the reply filed on 8-26-05 is acknowledged. Therefore, claim 60, is withdrawn from further consideration.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-22 stand rejected under 35 U.S.C. §102(b) as being anticipated by Klepinski (US 5,282,468, hereinafter "Klepinski"). Klepinski is considered to disclose:

a cuff device for contacting an electrode with a nerve, comprising an electrode that conforms to a portion of a nerve to avoid causing crush trauma, and having a means for connection to an electrical pulse. The disclosed structure is considered to anticipate the claimed electrode because both provide an electrode for establishing electrical contact with nerve tissue without causing increased nerve damage or irritation.

Claims 41-53 stand rejected under 35 U.S.C. §102(b) as being anticipated by Chen et al. (US 5,690,691, hereinafter "Chen"). Chen is considered to disclose a nasogastric tube electrode comprising a nasogastric tube having an inflatable means of expanding an electrode and an electrode attached to said collar so that when the collar is inflated, the electrode contracts the inner surface of the esophagus, and a means of supplying an electric pulse to said electrode (see col. 2, ln. 25-35, Chen). Chen discloses an electrode positioned within a nasogastric device to assist in supplying an electric pulse.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16 stand rejected under 35 U.S.C. §102(e) as being anticipated by Metzger et al. (US 5,117,828, hereinafter "Metzger"). Metzger is considered to disclose:

a catheter device for delivering an electric pulse to a nerve (see abstract and col. 2, ln. 14-20, Metzger). The disclosed catheter is considered to anticipate the claimed catheter because both carry electrically conducting members capable of transmitting to nerves. Further, Metzger discloses conductive members carried at the distal end of the body portion that can be electrically coupled to other devices at the proximal end by means of electrical wires or coupling members extending axially along the interior portion;

comprising a distal region and a proximal region, said distal region having at least one expandable electrode and an electrode expanding means (see col. 1, ln. 25-35 and col. 2, ln. 15-20, Metzger). The disclosed electrode is considered to anticipate the claimed expandable electrode because provide improved contact between the interior surface of the nerve and the conducting elements of the electrode;

said proximal region having an electrical connecting means for applying an electric pulse to the expandable electrode (see col. 2, ln. 45-50, Metzger). The

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disclosed connecting means is considered to anticipate the claimed means because both allow electrical signals to be applied to the electrode members.

Claims 17-20 stand rejected under 35 U.S.C. §102(e) as being anticipated by Taylor et al. (US 6,381,499 B1, hereinafter "Taylor"). Taylor is considered to disclose:

a clip electrode for attachment to a nerve, comprising a pair of electrically non-conducting members secured together in a pivotal relation so as to form confronting jaws (see col. 5, ln. 20-30, Taylor). The electrodes of Taylor are considered to anticipate the claimed clip electrode because both are use to stimulate the vagus nerve;

wherein at least one electrode is attached to an electrically non-conducting member (see col. 2, ln. 25-30, Taylor). The disclosed clip or probe means efficiently electrically couples the nerve stimulating device or insulating pacing wires to the vagus nerve;

and having a means for connection to an electric pulse means and wherein the electrode is shaped to avoid causing crush trauma to the nerve (see col. 2, ln. 10-30, Taylor). Taylor is considered to anticipate the claimed connection means because both work to provide stimulation that can be accomplished by first gaining access to the vagus nerve in the chest preferably via the thoracotomy used in the surgery, or in the neck through endoscopic procedures or through a small incision. The access route prevents trauma that can be caused to the nerve.

Claims 24-27 stand rejected under 35 U.S.C. §102(e) as being anticipated by Hill et al. (US 6,449,507 B1, hereinafter "Hill"). Hill is considered to teach:

an electrode array device for delivering a transdermal electric pulse to a nerve comprising electrically non-conductive material having a plurality of electrodes thereon,

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wherein the electrodes are electrically connected to a means of supplying an electric pulse (see col. 7, ln. 29-42 and col. 8, ln. 20-38, Hill). The disclosed electrode array is considered to anticipate the claimed device because both are used to make electrical contact with the nerve.

With reference to claims 28-30, Hill is considered to teach:

a endotracheal tube electrode device comprising an endotracheal tube having an inflatable means of expanding an electrode, and at least one electrode thereon so that the electrode contacts the tracheal wall when the means of expanding the electrode is inflated, and wherein the electrode has a means for connection to an electrical pulsing means (see col. 3, ln. 24-35, Hill). Hill teaches a nerve stimulator comprising endotracheal electrodes.

Referring to claims 54-59, Hill is considered to disclose:

an interrogator means, a cardiac pacer means electrically linked to said interrogator means, a cardiac monitoring means electrically linked to said interrogator means; a pulse generator means electrically linked to said interrogator means (see col. 6, ln. 20-55 and col. 10, ln. 49-65, Hill). Hill discloses a cardiac stimulator, which may be used to stimulate the heart as desired and configured to synchronize activation of regulators with pacing.

a means of administering an effective dose of pharmaceutical composition to a patient to prolong cardiac asystole, wherein the means of administration is electrically linked to said interrogator means (see col. 9, ln. 39-55, Hill). Hill teaches the delivery of pharmacological agents to produce reversible asystole of a heart;

wherein the interrogator automatically sends a signal to the electrode and observed the response on the cardiac monitoring means to determine optimum location of the electrode (see col. 3, ln. 58-65, Hill). Hill teaches a device that includes a processor connected to a transvenous nerve stimulation electrode and a cardiac stimulation electrode, which assist in signal processing to determine the ultimate electrode placement.

### ***Conclusion***

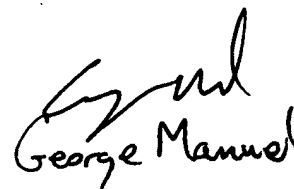
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene

  
George Mannes